OBJECTIVES: To assess the relative efficacy of umeclidinium bromide 62.5 mcg OD (UMEC) versus tiotropium bromide 18 mcg OD (TIO), aclidinium bromide 400 mcg BID (AB) and glycopyrronium bromide 50 mcg OD (GLYCO). **METHODS:** A systematic literature review was performed to identify RCTs ≥ 12 weeks duration comparing TIO, AB, GLYCO or UMEC to placebo in adult patients with COPD. Random effects meta-analyses were performed by pooling results of each treatment vs. placebo on change from baseline at 12 and 24 weeks in trough FEV1, SGRQ total score, TDI focal score and rescue medication use. The results were synthesized by using an indirect treatment comparison (ITC) within a frequentist framework based on the Bucher method. Scenario analyses were performed to evaluate the robustness of the results to variations in the included studies and assumptions. **RESULTS:** At 12 weeks, ITC results show that treatment with UMEC resulted in a comparable but numerically higher change from baseline in trough FEV1 compared to TIO [18.06mL (95%CI: -19.11, 55.23, p=0.341)], AB [35.77mL (95%CI: -7.84, 79.38, p=0.108)] and GLYCO [27.86mL (95%CI: -8.74, 64.45, p=0.136)]. At 24 weeks, UMEC resulted in comparable trough FEV1 values vs. TIO (p=0.854), AB (p=0.663) and GLYCO (p=0.777). UMEC also resulted in comparable TDI focal scores and rescue medication use at both time points compared with TIO, AB and GLYCO. UMEC resulted in numerically lower (better) change from baseline at 12 weeks in SGRQ total score compared with TIO [-2.65 (95%CI: -7.09, 1.79, p=0.242)], AB [-2.68 (95%CI: -7.12, 1.75, p=0.235)] and GLYCO [-2.15 (95%CI: -6.60, 2. 31, p=0.345)]. At 24 weeks there was no statistically significant difference in change from baseline in SGRQ total score between UMEC, TIO, AB and GLYCO. **CONCLUSIONS:** UMEC showed comparable efficacy to TIO, AB and GLYCO on trough FEV1, SGRQ, TDI and rescue medication use at 12 and 24 weeks.

PRS6

SYSTEMATIC REVIEW OF OBSERVATIONAL STUDIES AND RCTS OF OMALIZUMAB IN SEVERE PERSISTENT ALLERGIC ASTHMA AND META-ANALYSIS FEASIBILITY ASSESSMENT

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OBJECTIVES: To compare the effectiveness of omalizumab versus standard of care (SOC) based on randomized controlled trials (RCTs) compared with 'real-world', single cohort, observational studies that assess patients 'before and after' the use of omalizumab. **METHODS:** A systematic literature review was conducted to identify RCTs and observational studies that assessed omalizumab in patients with severe persistent allergic asthma. Study and patient characteristics, outcome definitions, and differences in baseline risk and observed study effects were compared in terms of exacerbations and hospitalizations across the RCTs and observational studies. **RESULTS:** 11 RCTs and 24 observational studies were identified. A wide range of clinically significant exacerbation rates was observed across RCTs in terms of baseline risk (SOC: 0.40–2.86) and the treatment effect (rate ratio [RR]: 0.39–0.75). This differed from observational studies in terms of baseline risk (before omalizumab: 3.48–6.00) and the treatment effect (RRs: 0.12–0.46). A limited range of severe exacerbation rates was observed in RCTs regarding baseline risk (SOC: 0.42–0.48) and the treatment effect (RR: 0.50–0.56). However, considerable differences were identified in observational studies in terms of baseline risk (before omalizumab: 2.20–4.50) and the treatment effect (RR: 0.05–0.39). In terms of hospitalization rates, a limited range was observed for RCTs with respect to baseline risk (SOC: 0.12–0.17) and the treatment effect (RR: 0.12–0.54). Again, a wider range was observed across the observational studies in terms of baseline risk (before omalizumab: 0.32–4.45) and the treatment effect (RR: 0.09–0.71). **CONCLUSIONS:** 'Real-world' evidence reinforces the efficacy of omalizumab in patients with severe allergic asthma derived from RCTs, although differences in potential treatment effect modifiers were identified. Patients in observational studies may represent a more severe population compared with those in RCTs.

PRS7

IMPACT OF OMALIZUMAB ON POOR ASTHMA CONTROL EVENTS AND MEDICATION UTILISATION IN PATIENTS WITH MODERATE OR SEVERE PERSISTENT ASTHMA

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OBJECTIVES: Poor asthma control is associated with increased health care cost in patients with moderate or severe asthma. Here we evaluate the impact of omalizumab on poor asthma control events (PACE) and medication utilisation (MU) in a case-crossover study of US patients with moderate or severe persistent asthma. **METHODS:** Truven MarketScan database was used to compare PACE (hospitalisation, ER visit, corticosteroid [CS] burst or ≥7 short-acting beta-agonist [SABA] fills) and MU for 1 year pre/post omalizumab exposure, during the period 1-January-2007 to 30-September-2012. Included in the analysis were patients aged ≥12 years who had 1 inpatient or 2 outpatient Asthma claims (ICD-9=493. XX) and used omalizumab continuously for 1 year, with 2 years continuous coverage (1 year pre/post omalizumab index date). Patients were categorized as Moderate or Severe based on their most recent 8 weeks of continuous, NHLBI-guideline-recommended, therapy preceding omalizumab. **RESULTS:** In total, 429 patients (mean age, 46.6 years; female, 59.0%; Moderate=340, Severe=89) were included in the analysis. Omalizumab was associated with reductions in proportions of All, Moderate, and Severe asthma patients with PACE (41.3%, 48.3%, 17.2%, respectively; all p<0.05). Specifically, reductions in patients with ≥1 asthma-related hospitalisation, ≥1 asthma-related ER visit, ≥2 CS bursts, and ≥7 SABA fills in the Moderate group (Moderate: 55.9%, 77.8%, 53.8%, and 40.6%, respectively; all p≤0.0196) drove reductions in All patients (all p≤0.0159). Reductions in patients with ≥1 OCS fill and ≥1 SABA fill were observed in All and Moderate patients (20.3%–26.1%; all p<0.0001); reductions in mean OCS fills and mean SABA fills were observed in All and Moderate patients (26.0%-42.5% p<0.0001), while reductions in mean SABA fills were also observed in Severe patients (20.1%; p=0.0328). **CONCLUSIONS:** Omalizumab initiation was associated with significant reduction in PACE and MU in patients with moderate or severe persistent asthma.

PRS8

INDIRECT COMPARISON OF EXACERBATION FREQUENCY BETWEEN ACLIDINIUM AND TIOTROPIUM IN PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE

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OBJECTIVES: The purpose of this study is to compare the frequency of exacerbations between aclidinium and tiotropium in patients with chronic obstructive pulmonary disease (COPD). **METHODS:** Through a systematic literature search in Medline (PubMed), we included randomized controlled trials that evaluated the exacerbation frequency of aclidinium 200μg and 400μg twice a day and tiotropium 18μg once a day regimens compared to placebo. Inclusion criteria were at least 12 weeks of treatment from January 1990 to January 2014, an age over 40, current or former smokers, and diagnosis with moderate to very severe COPD. The main outcome is the frequency of exacerbation. Indirect comparison analysis was performed to estimate the odds ratio of exacerbation between aclidinium and tiotropium. **RESULTS:** After screening 278 full-text articles, we identified 19 clinical trials that total 19,741 COPD patients were participated: 3 trials of aclidinium 200μg and 400μg BID and 16 trials of tiotropium 18μg QD. tiotropium 18μg was associated with a significant reduction in exacerbation compared with placebo (OR 0.90; 95% CI 0.84 to 0.96). Other two anticholinergic agents showed comparable effects in reducing exacerbation compared with placebo: aclidinium 200μg (OR 0.73; 95% CI 0.53 to 1.01) and aclidinium 400μg (OR 0.72; 95% CI 0.52 to 1.00). Aclidinium 200μg (OR 0.84; 95% CI 0.603-1.167) and aclidinium 400μg (OR 0.83; 95% CI 0.592 -1.156) BID showed the similar frequency of exacerbation to tiotropium 18μg QD. **CONCLUSIONS:** Our study substantiates that tiotropium 18μg provides superior effects on lowering the risk of exacerbation compared with placebo but there was no significant difference in the frequency of exacerbations between aclidinium and tiotropium.

PRS9

TREATMENT PLAN COMPARISON: AN OBSERVATIONAL STUDY OF THE MARCHE REGION

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OBJECTIVES: To estimate the number of users of Theophylline (ATC: R03DA04) and Doxofylline (ATC: R03DA11) for the treatment of chronic asthma in adults, in the Marche Region. Moreover, we wanted to estimate the cost of the two treatments, taking into account the prescriptions of other drugs associated with them. **METHODS:** The drug prescriptions were extracted from the Information System of the Pharmaceutical Prescriptions of the Marche Region (PHARM), containing all the recipes sent by pharmacies within the region and reimbursed by the National Health System. The number of prescriptions per year has been obtained by selecting all the recipes for each ATC code in the years 2008-2012, while the number of users has been estimated by identifying the subjects who received at least one prescription of the ATC codes of interest. The number of concomitant prescriptions was estimated by selecting all the recipes for potentially associated ATC, dispenced between 5 days before and 5 days following the prescription of ATC codes. The price of prescriptions has been calculated using the information "price" contained in the PHARM record. **RESULTS:** For both drugs, the users are approximately 5,000 per year in the study period. Theophylline had a mean base price lower than Doxofylline (4.81€ vs 6.37€ per prescription); however, Theophylline was more associated than Doxofylline (34.4% vs 23.7%) with other drugs for the treatment of Asthma. Consequently, the total treatment cost for Theophylline was equal to 33.65€ vs a total cost for Doxofylline equal to 22.49€ (+ 49.6%). **CONCLUSIONS:** The PHARM allows the estimate of drugs' utilization, taking into account the overall patient's treatment plan. In our study, the prescription of the first ATC code is more associated with prescriptions of other drugs, and this implies an increasing in the cost of the treatment plan despite a lower average initial price.

PRS10

A DATABASE STUDY TO INVESTIGATE THE INCIDENCE OF ANAPHYLAXIS AND THE PRESCRIPTION RATE OF SELF-INJECTION EPINEPHRINE IN JAPAN

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OBJECTIVES: A database research was conducted to investigate the incidence of anaphylaxis/shock using a Japanese health-claims database (HDB). In addition, the prescription rate of self-injection epinephrine was investigated among those patients with anaphylaxis for the management of future reactions. **METHODS:** A Japanese HDB which contains approximately 1.8 million subjects covered by employment-based health insurance (MinaCare Co. Ltd) was used for this retrospective study. In order to identify actual anaphylaxis/shock precisely, diagnosis recorded in the claims based on ICD-10 code (T78.0, T78.2 and T88.6) was combined with claim records of medical practice and prescriptions. Specifically, prescription for epinephrine/adrenaline or oxygen inhalation therapy was required for "anaphylactic shock" and the use of an infusion therapy or venous catheter was required for detecting "anaphylaxis (except for anaphylactic shock)". For this study, the data associated with events occurring in fiscal years 2010 to 2013 (2010/4/1 to 2013/3/31) were included. **RESULTS:** Of approximately 2.9 million person-years of observations, 13.3 anaphylactic shock events per 100,000 person-years (crude rate) were identified. The rate was 42.9 per 100,000 person-years when non-shock anaphylaxis events were considered. The age-specific anaphylactic shock event rates (per 100,000 person-years) were: 27.6 (0-6 years), 12.8 (7-12 years), 11.0 (13-18 years), and 11.9 (>18 years). Among the 389 anaphylactic shock events, etiologies of anaphylaxis were food 113